

ETCTN Cancer Trials Support Unit Information Page

1. Introduction

The Cancer Trials Support Unit (CTSU) is a service of the NCI that supports clinical trial management and conduct. The CTSU provides services to several Cancer Therapy Evaluation Program (CTEP)-supported networks, including the ETCTN. Services provided by the CTSU include:

- Institution and person roster support;
- CTSU website support for posting of protocols and information dissemination;
- Site registration and regulatory document tracking and management support;
- Patient enrollments through the Oncology Patient Enrollment Network (OPEN);
- National Coverage Analysis (NCA) and Electronic Medical Record (EMR) support for select trials;
- Clinical Data Management Support (CDMS) for the Medidata Rave data management system via the CDMS Support Center (CSC);
- Single-sign-on access directly from the CTSU website to other applications necessary to conduct an ETCTN trial (e.g., OPEN, Rave); and
- Customer service support through the Help Desk for regulatory, membership, and patient registration services.

All **new** trials opened under the ETCTN program will receive full CTSU support.

Trials activated **prior to** the implementation of the ETCTN program that have not transitioned into the ETCTN will continue to follow their existing procedures for the areas listed above (even if they are handled through the CTSU). Sites will be notified in advance if there are trials identified for transitioning into the ETCTN.

Each protocol document will include logistical information on the conduct of the trial, including which CTSU support services are being used.

2. Person Registration and Account Maintenance

Refer to the [Registration Procedures and CTSU Website Access](#) page for information on person registration with CTEP and the CTSU. In summary:

- Active CTEP registration with the credentials necessary to access secure NCI/CTSU Information Technology (IT) systems, and when applicable, be registered with CTEP in the Registration and Credential Repository (RCR). Refer to the [RCR guide](#) for more information and/or navigate directly to the [RCR system](#).

- Several CTSU-coordinated applications require specific user roles to gain access. These applications include OPEN, Rave, and the Transfer of Image and Data (TRIAD) system. Organizational affiliations may be viewed on the CTSU website under the Roster Update Management System (RUMS) section. For some roster members (i.e., Site Administrators and Site Data Administrators), functionality is available via RUMS to maintain roles and request the addition or withdrawal of persons. For more information on rosters and roles, refer to the [Rosters and Roles for ETCTN Participants \(Institution Rosters and Person Rosters\) Information Page](#).

3. CTSU Communications

Refer to the [ETCTN Protocol Access and Communication Information Page](#) for more information on protocol posting on the CTSU website. In summary:

- After registering with CTEP and credentialing by the CTSU, access the CTSU members' website from the login box on the public home page of the [CTSU website](#). The CTSU members' website contains a central repository of protocol documents and associated materials. It also includes sections for site roster management, regulatory submissions, accrual, data management, and general CTSU educational materials. In addition, the website includes sections for OPEN and Rave, which provide access to those applications as well as additional resources.
- The CTSU Bi-Monthly Broadcast is the primary way of communicating study-related updates to clinical sites including study status changes, arm and cohort closures, safety notifications, and amendments. The Bi-Monthly Broadcast is released on the 8th and 22nd of each month via email and is posted to the CTSU website.
- The CTSU also communicates using targeted broadcasts and newsletters. Targeted broadcasts are used to reach investigators and research associates on important trial-specific communications between the Bi-Monthly Broadcasts. The CTSU newsletters are sent three times a year and contain detailed information about new and ongoing CTSU initiatives.

4. Regulatory Document Submission

Refer to the [ETCTN Regulatory Processing Information Page](#) for more information on central regulatory processing through the CTSU. In summary:

- Lead Protocol Organizations (LPOs) use the CTSU's Regulatory application to identify all the regulatory requirements for a given protocol. Compliance with these protocol-specific requirements (PSRs) will dictate each site's registration status. All site registration documents will be submitted to the CTSU Regulatory Office where they will be reviewed and entered into the Regulatory application (IRB approvals, but not other PSRs, will be submitted automatically for sites participating in the NCI CIRB program). Once an institution has complied with all the PSRs for a study, the site will be designated with an approved site registration status in the Regulatory application.

- The CTSU does not send formal notification when sites have an approved status in the Regulatory application. Site registration status may be checked for affiliated sites by querying the Site Registration section located under the Regulatory area of the CTSU members' website.

5. Patient Enrollment

Refer to the [ETCTN Patient Enrollment Information Page](#) for more information on the CTSU's patient enrollment system, including the integration with Theradex's Interactive Web Response System (IWRS) for slot reservations and cohort management. In summary:

- Patient registration is conducted using OPEN as outlined in the Registration Procedures section of the protocol and in the [OPEN section](#) of the CTSU members' website. Enrollments may be credited to an organization participating on the study in which the institution and the credited investigator are active members.
- Enrollments must be performed by site staff with an active CTEP registration status with the credentials necessary to access secure NCI/CTSU IT systems and the Registrar role on an ETCTN roster. Access OPEN from the CTSU website or using the [OPEN URL](#). A user guide and training are available in the OPEN section of the CTSU members' website and within the [OPEN portal](#).

6. NCA and EMR Documents

The CTSU supports the development and maintenance of NCA templates for select ETCTN trials. The CTSU follows national coverage determinations as defined by Medicare and the National Comprehensive Cancer Network guidelines as the basis for coverage analysis development. A standardized NCA template (Excel format) is used for all NCAs developed by the CTSU. The NCAs are provided as a guidance tool for institutions to assist with billing compliance. Institutions that chose to use these tools are responsible for the verification and modification of the coverage analysis in compliance with their institutional guidelines. Site staff are ultimately responsible for modifications specific to their local coverage determinations.

The CTSU also supports the development and maintenance of EMR template spreadsheets for select ETCTN trials. Research trials are set up in an institution's EMR System (e.g., Epic, Cerner) for patient scheduling, drug ordering, data collection, and billing. A CTSU EMR template functions as a study-specific order set or treatment plan and assist sites in configuring their EMR application to accept study participants. By providing the protocol's elements that are most relevant to the EMR, the template attempts to decrease protocol start-up time and use of resources at the site level.

Upon trial activation the study-specific EMR Template, EMR Template Guide, and Coverage Analysis Worksheet are posted on the protocol-specific page on the CTSU members' website under *Documents > Protocol Related Documents > Education and Promotion* (use the protocol tree or *Document Type* filter). The CTSU Bi-Monthly Broadcast includes announcements of newly posted or revised NCAs and EMR templates.

7. Data Management

Refer to the [ETCTN Data Management Information Page](#) for more information on the centralized data management system. In summary:

- Data for all new trials will be entered and queries managed electronically by LPOs using the Rave electronic data capture system. The iMedidata portal controls access to studies in Rave based on the CTEP Identity and Access Management system, role assignments in the Roster Maintenance application, and completion of Rave eLearning assignments. Instructions for accessing Rave are provided on the Rave page located in the [Data Management section](#) of the CTSU members' website.
- Information regarding iMedidata accounts, Frequently Asked Questions, and other helpful resources and announcements can be found within the Rave page located in the [Data Management section](#) of the CTSU members' website as well as on the [Theradex website](#).

8. CTSU Contact Information

CTSU Regulatory Office (for regulatory questions):

Phone: 1-866-651-CTSU (1-866-651-2878)

Email: CTSURegHelp@coccg.org

CTSU Help Desk:

Phone: 1-888-823-5923

Email: ctsucontact@westat.com

All calls and correspondence will be triaged to the appropriate CTSU representative.

CTSU Help Desk hours are 9:00 am – 6:00 pm ET Monday-Friday (excluding holidays).

Patient eligibility or treatment-related questions should be directed to the LPO designee indicated in the protocol document.